

TITLE 410 INDIANA STATE DEPARTMENT OF HEALTH

LSA Document #11-458

SUMMARY/RESPONSE TO COMMENTS FROM THE PUBLIC HEARING

The Indiana State Department of Health's (ISDH) Executive Board preliminarily adopted Rule 410 IAC 1-6, Offering of Human Immunodeficiency Virus Information and Counseling and Human Immunodeficiency Virus Testing and 410 IAC 1-7, HIV Counseling and Testing of Pregnant Women, on September 14, 2011. ISDH published the proposed rule in the November, 2011 Indiana Register. A public hearing was held in Indianapolis on January 26, 2012, to solicit comments from the public on the proposed rule. The record of the hearing was held open for submission of written comments, until January 26, 2012. The following parties made comments during the public hearing or submitted written comments:

Danielle Osterholzer, MD -- Assistant Professor of Clinical Medicine and Pediatrics, Indiana University School of Medicine Adult and Pediatric Infectious Diseases (Dr. Osterholzer)

Elaine Cox, MD -- IU Health and Ryan White Center for Pediatric Disease at Riley Hospital (Dr. Cox)

The following is a summary of the comments received and ISDH's responses thereto:

Comment: Dr. Osterholzer asked if the code requires the provider to document in the chart that counseling was given and commented that she is concerned that Sec. 7 (a) (1) will lead to practices that make pregnant women sign a piece of paper saying they received counseling about HIV which is a barrier.

Response: Yes, IC 16-41-6-8 (i) (2) requires the physician, advanced practice nurse, or the designee of the physician or advanced practice nurse who orders an HIV test under section 5 or 6 of Chapter 16 to document "that the pregnant woman was *counseled* and provided the required information set forth in subsection (b) to ensure that an informed decision was made."

Comment: Regarding Sec. 7(a) (1), Dr. Osterholzer asked if the requirement to "document" in the medical record is in the code or if it is only in the rule and asked if it could be stricken from the rule. Dr. Osterholzer also expressed concern that requiring information and counseling regarding HIV to be documented in the medical record will prompt some groups to make a woman sign a piece of paper stating that she got this education and counseling.

Response: Yes, IC 16-41-6-8 (i) (2) requires the physician, advanced practice nurse, or the designee of the physician or advanced practice nurse who orders an HIV test under section 5 or 6 of Chapter 16 to document "that the pregnant woman was *counseled* and provided the required information set forth in subsection (b) to ensure that an informed decision was made." Since documentation that the pregnant woman has been counseled is required by code, ISDH does not wish to strike Sec. 7 (a) (1) but offers a revision which reads "[i]nformation and

counseling regarding human immunodeficiency virus (HIV) and the standard licensed diagnostic test for HIV.”

Comment: Dr. Cox commented that the requirement in Sec. 7 to document in the medical record that the prenatal care provider provided counseling to the pregnant patient should be clarified to specify that no written consent or written attestation from the patient that the counseling occurred is necessary.

Response: ISDH agrees. Revisions have been made to Sec. 7 (a) (1) and Sec. 7 (b).